UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MEMORANDUM

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Date: 2/26/2019 revised from the review dated 12/18/2018

Subject: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1,
EPA Reg. No. 63761-8 (DP Barcode: 448835, E-Submission: 32134)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P)
Date signed: 12/17/2018

To: Terria Northern / Zeno Bain
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Sterilex LLC
111 Lake Front Drive
Hunt Valley, MD 21030

Formulation from the Label:

Active Ingredient(s)	% by wt.
n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride	3.0%
n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5% dimethyl benzyl ammonium chloride	3.0%
Hydrogen Peroxide (35%)	6.3%
Other Ingredients	87.7%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Liquid Concentrate

Submission type: Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, fungicidal), non-food contact sanitizer, and fungistat/mildewstat liquid concentrate product for hard, non-porous surfaces at varying contact times.

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Requested action(s): Addition of virucidal, biofilm, and emerging viral pathogen claims

Documents considered in this review:

- Letter from applicant to EPA dated September 6, 2018
- Emerging Viral Pathogen Letter dated November 9, 2018
- Data Matrix (EPA Form 8570-35)
- 5 efficacy studies (MRID 50673201 – 50673205, 49809105 and study ID GLP2037 no MRID)
- Proposed label dated 11/19/2018
- Proposed label dated 02/01/2019
- Confidential Statement of Formula (EPA Form 8670-4) dated 03/11/2016

II PROPOSED DIRECTIONS FOR USE

"GENERAL ONE STEP DISINFECTION AND CLEANING DIRECTIONS FOR HARD, NON-POROUS SURFACES

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step, cleaner and hospital-use disinfectant at 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 – 16.0 [378.5 – 473.2 ml] fl. oz. of Sterilex Ultra Activator Solution per gallon [3.79 L] of water (1:1:10 – 1:1:8), or equivalent use dilution. [If high foam is desired, refer to High Foam Application Instructions.] Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus organic soil against:"

"APPLICATION INSTRUCTIONS:

To clean and disinfect in one step, remove gross [filth] [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Activator Solution per gallon [3.79 L] of water. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system, mopping or immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface. [If high foam is desired, refer to High Foam Application Instructions.] Do not breathe spray. Allow surfaces to remain wet for at least 10 minutes. Rinse all food contact surfaces thoroughly with a potable water rinse. Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. [For initial start-up, repeat on all surfaces for [3] [3-5] consecutive {nights, treatments}]. [For routine maintenance applications treat all surfaces 1x/week, or as needed to maintain environmental counts.]

[TOUGH][HEAVY DUTY] [SOIL] [INANIMATE SCUM] [INANIMATE MATERIAL] REMOVAL APPLICATION INSTRUCTIONS

Preclean surfaces per the Precleaning Instructions. Mix 64.0 fl. oz. [1892.7 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 64.0 fl. oz. [1892.7 ml] of Sterilex Ultra Activator Solution per gallon [3.79 L] of water (1:1:2), or equivalent use dilution. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, spraying, sponging, mopping, or immersion. Allow surfaces to remain

wet for at least 10 minutes. Do not breathe spray. Rinse all food contact surfaces thoroughly with a potable water rinse. Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. For a more concentrated option, prepare a 1:1 solution by mixing equal parts Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. Do not use Ultra Soft Metal Activator at the 1:1 or 1:1:2 application rate."

"Kills Biofilm Bacteria [on] [in] [*insert hard, non-porous use site*]

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, effectively penetrates biofilm and kills the following biofilm bacteria:

[*Pseudomonas aeruginosa* (*Pseudomonas*) [ATCC# 15442]]

[*Staphylococcus aureus* (*Staph*) [ATCC# 6538]]

APPLICATION INSTRUCTIONS:

Apply Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution as a disinfectant, per the [Tough][Heavy Duty][Soil] [Inanimate Scum] [Inanimate Material] Removal Application Instructions. Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution."

III STUDY SUMMARIES

1.	MRID	50673201	Study Completion Date:	08/06/2018
Study Objective		Disinfectant, virucidal		
Testing Lab; Lab Study ID		Microbac, 971-102		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory		
Indicator Cell Culture		Vero, ATCC CCL-81		
Test Method		Virucidal Hard-Surface Efficacy Test		
Application Method		Liquid concentrate		
Test Substance Preparation	**Name/ID**	Sterilex Ultra Activator Solution		
	Lots **☐ 1 ☒ 2 ☐ 3**	RS1-189A, RS1-188B		
	Preparation	Tested concentration: LCL Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent) Diluent: 400 ppm AOAC Hard Water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Glass petri dish, 1 per lot		
Test conditions		**Contact time**	9-min 45-sec	**Temp** 21°C **RH** 45.4-46%
Neutralizer		Sephacryl gel filtration		
Reviewer comments				

2.	MRID	50673203	Study Completion Date:	05/08/2018
Study Objective		Biofilm		
Testing Lab; Lab Study ID		Microchem, GLP1910		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Pseudomonas aeruginosa (ATCC 15442)		
Test Method		Evaluation of Disinfectant Efficacy against a Biofilm - Single Tube Method		
Application Method		Liquid concentrate		
Test Substance Preparation	**Name/ID**	Sterilex Ultra Activator Solution		
	Lots **☐ 1 ☐ 2 ☒ 3**	RS1-188A, RS1-188B, RS1-189A		
	Preparation	Tested concentration: LCL Dilution: 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent) Diluent: 400 ppm AOAC Hard Water		
Soil load		N/A		
Carrier type, # per lot		Glass coupon carriers, 5		
Test conditions		**Contact time**	9-min 45-sec	**Temp** 21°C **RH** N/A
Neutralizer		2X Dey/Engley Broth supplemented to contain 5.0% Tween 80 and 5.0% Catalase (76.0 ml)		
Reviewer comments (i.e. protocol deviations, etc)				

3.	**MRID**	50673204	**Study Completion Date:**				05/25/2018
Study Objective		Biofilm					
Testing Lab; Lab Study ID		Microchem, GLP1914					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Staphylococcus aureus (ATCC 6538)					
Test Method		Evaluation of Disinfectant Efficacy against a Biofilm - Single Tube Method					
Application Method		Liquid concentrate					
Test Substance Preparation	**Name/ID**	Sterilex Ultra Activator Solution					
	Lots **☐ 1 ☐ 2 ☒ 3**	RS1-188A, RS1-188B, RS1-189A					
	Preparation	Tested concentration: LCL Dilution: 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent) Diluent: 400 ppm AOAC Hard Water					
Soil load		N/A					
Carrier type, # per lot		Glass coupon carriers, 5					
Test conditions		**Contact time**	9-min 50-sec	**Temp**	21°C	**RH**	N/A
Neutralizer		2X Dey/Engley Broth supplemented to contain 5.0% Tween 80 and 5.0% Catalase (76.0 ml)					
Reviewer comments (i.e. protocol deviations, etc)							

4.	**MRID**	50673205	**Study Completion Date:**				02/15/2018
Study Objective		Disinfectant, virucidal					
Testing Lab; Lab Study ID		Accuratus, A24854					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL					
Indicator Cell Culture		MARC-145 cells					
Test Method		Virucidal Hard-Surface Efficacy Test					
Application Method		Liquid concentrate					
Test Substance Preparation	**Name/ID**	Sterilex Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution					
	Lots **☐ 1 ☒ 2 ☐ 3**	RS1-188B, RS1-189A					
	Preparation	Tested concentration: LCL Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent) Diluent: 400 ppm AOAC Hard Water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass petri dish, 1 per lot					
Test conditions		**Contact time**	9-min	**Temp**	20°C	**RH**	N/A
Neutralizer		Letheen Broth supplemented with 0.1% Sodium Thiosulfate,1.0% Tween 80, and 1% Catalase					
Reviewer comments		cytotoxicity control was performed with spray application.					

5.	**MRID**	N/A	**Study Completion Date:**		11/19/2018
Study Objective		Disinfectant, additional bacteria			
Testing Lab; Lab Study ID		Microchem, GLP2037			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Cronobacter sakazakii (ATCC 29004)			
Test Method		AOAC Use-Dilution Method			
Application Method		Liquid concentrate			
Test Substance Preparation	**Name/ID**	Sterilex Ultra Activator Solution			
	Lots **☐ 1 ☐ 2 ☒ 3**	RS1-188B, RS1-188A			
	Preparation	Tested concentration: LCL Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent) Diluent: 400 ppm AOAC Hard Water			
Soil load		5%			
Carrier type, # per lot		stainless steel penicylinder carriers, 10			
Test conditions		**Contact time**	9-min	**Temp**	20°C **RH** N/A
Neutralizer		Letheen Broth additionally supplemented to contain 0.1% Catalase			
Reviewer comments (i.e. protocol deviations, etc)					

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			RS1-188B	RS1-189A	
9-minute 45-second contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water, 5% soil load					
50673201	New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory	10^{-3} dilution	Cytotoxicity	Cytotoxicity	7.10
		10^{-4} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤3.10	≤3.10	
		Log Reduction	≥4.00	≥4.00	
9-minute contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water, 5% soil load					
50673205	Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL	10^{-1} dilution	Cytotoxicity	Cytotoxicity	5.50
		10^{-2} to 10^{-8} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤1.50	≤1.50	
		Log Reduction	≥4.00	≥4.00	

Disinfection – Biofilm

MRID	Organism	Log_{10} Reduction			Average log_{10} CFU/Carrier
		Batch RS1-188A	**Batch** RS1-188B	**Batch** RS1-189A	
9-minute 45-second contact time, 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent of 400 ppm AOAC Hard Water)					
50638403 (03/23/18)	*Pseudomonas aeruginosa* (ATCC 154421)	≥6.96			8.68
(03/29/18)			≥7.58		8.07
(03/30/18)				≥8.52	8.52
50638404 (04/05/18)	Staphylococcus aureus (ATCC 6538)	≥6.34	-	-	7.91
(05/03/18)		-	≥6.14	-	8.41
(05/04/18)		-	-	≥6.09	8.41

Disinfection – Additional Bacteria

MRID	Organism	Log_{10} Reduction		Average log_{10} CFU/Carrier
		Batch RS1-188A	**Batch** RS1-188B	
9-minute 45-second contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water), 5% soil load				
50638403 (11/14/18)	Cronobacter sakazakii (ATCC 29004)	0/10	0/10	4.01

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50673201	Disinfectant Virucidal	Hard, non-porous surfaces	Use-dilution	9-minutes 45-seconds	5%	1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent 400 ppm AOAC hard water)	• New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory	**Yes**
50673205				9-minutes			• Porcine Respiratory & Reproductive Syndrome virus, University of Kentucky, Strain NVSL	
50673203	Disinfectant Biofilm	Hard, non-porous surfaces	Use-dilution	9-minutes 45-seconds	N/A	1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent400 ppm AOAC hard water)	• Pseudomonas aeruginosa (ATCC 15442)	**Yes**
50673204				9-minutes 50-seconds			• Staphylococcus aureus (ATCC 6538)	
Not Yet Assigned	Disinfectant Additional Bacteria	Hard, non-porous surfaces	Use-dilution	9-minutes	5%	1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent 400 ppm AOAC hard water)	• Cronobacter sakazakii (ATCC 29004)	**Yes**

49809105 **49809107**	Emerging Viral Pathogen	Hard, non-porous surfaces	Use-dilution	9-minutes	5%	1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent 400 ppm AOAC hard water)	• Feline calicivirus, Strain F-9, ATCC VR-782 • Human Rotavirus (Group A), Strain Wa (TC-Adapted), ATCC VR-2018	**Yes**

VI LABEL COMMENTS

Label 02/01/2019:

1. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution virucidal disinfectant (1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)) against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

   New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory
   Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL

   These claims are **acceptable** as they are supported by the submitted data

2. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution Biofilm disinfectant (1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent)) against the following on hard, non-porous surfaces in the presence of no organic soil for a 10-minute contact time:

   Staphylococcus aureus (ATCC 6538)
   Pseudomonas aeruginosa (ATCC 15442)

   These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product, for Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution additional bacteria disinfectant (1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)) against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

   Cronobacter sakazakii (ATCC 29004)

   This claim is **acceptable** as it is supported by the submitted data

4. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated November 9, 2018:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rotavirus Feline calicivirus
Large, non-enveloped virus	Feline calicivirus

These claims are **acceptable** as they are supported by the cited data.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

On page 17 of the proposed label, remove “Include Adenoviridae, Reoviridae, and Papillomaviridea” and “Includes Arenaviridae, Bornaviridae, Bunyaviridae, Coronaviridae, Filoviridae, Flaviviridae, Hepadnaviridae, Herpesviridae, Orthomyxoviridae, Paramyxoviridae, Poxviridae, Retroviridae, Rhabdoviridae, and Togaviridae” listed in the table under the “Large Non-Enveloped Virus Families” and “Enveloped Virus Families”.

5. A change in the use directions and clarification on dilution clarification (see appendix 1) were provided to the agency in response to the efficacy review., the Based on that supporting information, the biofilm claim is acceptable at 1:1:2 and 1:1 dilution ration. The review has been updated to this decision.

6. Please make the following changes to the proposed label dated 2/01/2019. Unless otherwise noted below, the label changes specified in the original review dated 12/18/2019 were accepted by the registrant and the change is reflected on the revised label dated 2/1/2019, or the label revision provided by the registrant sufficiently addressed the agency concern.

   a) On page 4, remove the following references to an entire genus of bacteria: “Listeria” and “Salmonella.” Note, E. coli is an appropriate abbreviation as it clarifies the genus and the species of the bacteria. However, listing only the genus such as “Listeria” may be false or misleading to user as there are many types of Listeria. Registrant may choose to appropriately abbreviate the tested organism (ie. *L. monocytogenes*) to provide clarity to the user.

b) On pages 4, 6,14 and 17, use sites and directions for use on "freezers","ice machines" and "refrigerated trucks" should specify that surfaces must be at room temperature prior to disinfection or sanitization and/or used only on exterior surfaces. Testing was done at room temperature. Temperature extremes such as high heat or freezing temperatures may affect the chemicals ability to perform and/or contact time.

c) On page 5, remove the claims "removes biofilm matrix in addition to killing bacteria in biofilm" and "Biofilm removal reduces potential repopulation of biofilm bacteria". Claims for removal of public health biofilms are not supported by the biofilm method.

d) On page 5, non-public health biofilm claims should be clearly differentiated from public health applications including "[Removes** biofilm from [dental unit water] [animal drinking] [animal water] lines **laboratory studies show >90% removal]". These claims are still located in the general claims section on the master label and are not acceptable as they may be false or misleading to user. The agency stands by the decision and requests the registrant add "non-public health" to those biofilm claims.

e) On page 5, remove the claim "[Prevents and suppresses formation of biofilm in [dental unit water] [animal drinking] [animal water] lines]" as it is not an acceptable label change. The Agency requests the removal of all label language that may be misconstrued as a residual kill claim.

f) On page 5, remove the claim ""Clean. Disinfect. Protect" and "Protects against germs on hard, nonporous surfaces" as these imply protection from disease. The agency stands by the initial recommendation.

g) On page 6, qualify "Staphylocidal", "Psuedomonacidal", "Salmonellacideal" and "Listericidal" with a footnote to indicate the appropriate tested organisms.

h) On page 6, revise the claim "[Prevents][cross-contamination] [spread of germs][in high traffic areas]" to "Reduces cross contamination on treated surfaces in high traffic areas". Similarly revise the claim "Helps prevent the spread of [the flu] [animal][avian] viruses* [in food plant animal health facilities" to "helps reduce the spread of [flu] [animal] [avian] viruses* on treated surfaces". The Agency stands by its initial decision. Claims to prevent contamination are not supported by data.

i) On page 6, the Agency stands by its initial decision, remove the claim "is an effective aid in preventing many diseases of bacterial and viral origin". The product can claim to kill microorganisms substantiated by data; however, a product may not claim prevention or protection from disease.

j) On pages 10 and 11, with regard to the instructions for use to control non-public health, vegetative, spore-forming bacteria, we acknowledge that the response from the efficacy mailbox can be interpreted to indicate that claims for the vegetative form of spore forming organisms can be supported with data against the vegetative form of the spore forming organism. We should have clarified that for spore forming organisms, data should be generated with the spore form of the organism and not the vegetative form. Based on the response provided from the mailbox, these claims are acceptable at this time. Please not that for future submissions, all data for spore forming organisms should be generated against spores and submitted to the agency for review. In addition, you may be asked to remove this claim in the event that the agency publishes guidance to address this issue.

k) On page 13, rerevise label language to “non-public health biofilm removal in animal drinking lines” and “remove non-public health biofilms found in tanks...” Public health biofilm claims include hard non-porous surfaces only, water lines use a porous plastic and do not meet the criteria. Additionally, animal drinking lines are not public health sites.

APPENDIX 1: STERILEX RESPONSE TO EFFICACY REVIEW DATED 12/18/2018
The following response to the initial review dated, was provided by the registrant on .
Label Comment #2
Per the COA's provided in the submitted biofilm studies (MRIDs 50673203, 50673204), the initial concentrations of the GLP test substances were as follows:

Lot Number	% Quat	%Hydrogen Peroxide
RS1-188A	5.81	6.14
RS1-188B	5.82	6.03
RS1-189A	5.83	6.08

Since the GLP test substances had active ingredient concentrations above the allowable LCL range, additional water must be added to dilute the concentrations of active ingredient in the final test substance mixtures. If we were to translate the 1:1:2 dilution rate to a 36 mL total volume of test substance mixture, the ratio would be 9 mL Solution 1, 9 mL Activator, and 18 mL water. If we calculate the concentration of quat and hydrogen peroxide in a test substance mixture using Solution 1 test substance at the exact LCL, the calculations are as follows:

(5.757% x 9 mL Solution 1) / 36 mL Test Substance Mixture x (1000 mL/L) = 14.393 mL quat per liter of test substance mixture

(6.05% x 9 mL Solution 1) / 36 mL Test Substance Mixture x (1000 mL/L) = 15.125 mL hydrogen peroxide per liter of test substance

The active ingredient concentrations of the test substance mixtures are as follows:

Lot Number	Dilution Rate	Quat Concentration (mL/L test substance mixture)	Hydrogen Peroxide Concentration (mL/L test substance mixture)
RS1-188A	9:9:18.536	14.312	15.125
RS1-188B	9:9:18.395	14.392	14.911
RS1-189A	9:9:18.456	14.393	15.010

Through these calculations, Sterilex ensured that the biofilm studies were conducted with active ingredient concentrations below the LCL and disagrees with EPA's assessment that the studies were conducted at the nominal concentration.

Label Comment #5

a) Sterilex believes that the submitted biofilm studies support the 1:1:2 and 1:1 dilution ratio. In support of this statement, please reference the explanation and calculations provided in the response above.

b) i. Sterilex has remove the terms common and eliminates and added a notation to the referenced pathogens. The brackets have been added to the organisms to denote final marketing language that may choose to point out certain microorganisms rather than all four microorganisms. Sterilex has also added the option “such as” in case the claim is presented as a continuous sentence rather than a statement and a reference.
ii. Sterilex has removed all new language. With the exception of *E. coli* and *Listeria,* these abbreviated terms have been approved by EPA in previous label amendments and reviews.

c) Please clarify this request. Per the directions for use for individual quick freezing (IQF) freezers and ice making machines (page 17), all food contact surfaces must be rinsed following application.
   i. The biofilm label claims are located on the non-public health section of the product label and are very clearly associated with the non-public health use sites when included on a commercial label. This section of the label, including use sites and claims, do not list public health organisms or make any claims of disinfection/sanitization associated with public health efficacy. As part of the previous amendment, Sterilex added a “Biocide and Non-Public Health Use Sites” header to this section and the word “health” to the “non-public” terms in order to re-enforce the non-public health use site designation of these claims.
   ii. As a result of biofilm removal, this product reduces the potential for biofilm bacteria to repopulate a biofilm matrix in which bacteria has been killed, but the matrix remains intact. This claim relates to the biofilm matrix removal rather than residual control of bacteria that can inhabit the bacteria. Please review the proposed label changes for acceptability.
   iii. Please see proposed label changes.
   iv. The label has been revised.
   v. Harborage niche is any surface or location in which bacteria are able establish a biofilm matrix such as a welding joint, threads of a screw, pits/cracks in metal surfaces, etc. The term harborage niche is an industry recognized hotspot for microbial contamination and disinfection of those areas is a critical sanitation priority. Biofilm found in harborage niches are sources of reoccurring contamination in the plant. Sterilex requests that EPA permit this term to better communicate the products ability to kill biofilm bacteria.
   vi. Sterilex requests that EPA utilize the disinfection data on file to support this claim. This claim has been approved with the same disclaimer as recently as 2016 on EPA registered product labels such as Lavo (EPA Reg. No. 68338-2), CLB (EPA Reg. No. 5813-111), and PPD Puma (EPA Reg. No. 67619-32). Upon review of submitted data, Sterilex has identified no differences in the data submitted, or disinfection methods used, between this product and the three products referenced above. Sterilex requests that EPA

d) i. Sterilex requests that EPA reconsider the request to remove previously approved claims as this label language has been approved by EPA in numerous label amendments and reviews prior to this submission.

ii. This product is used as a critical intervention method for the entrance to a building, or production room, in order to prevent cross contamination on throughout the facility. Sanitization of entryway systems and waterproof footwear can ensure that harmful organisms do not move from a untreated surface/area in the plant into a different treated, or untreated, surface/area. This product, and similar products, are often the primary barrier to introduction of organisms.

iii. Please see response above.

iv. Please clarify this request. Per the directions for use for individual quick freezing (IQF) freezers and ice making machines (page 17), all food contact surfaces must be rinsed following application.

vii. The label has been revised. By changing the contact time to 10 minutes, the claim includes all virucidal claims so the asterisk has been removed from the end of the claim. The asterisk on "viruses" remains to reference the virucidal directions for use.

viii. This claim has been approved by EPA for the registered product, PUMA (EPA Reg. No. 5813-100) for the use of this product as a sanitizer and disinfectant. Sterilex believes that the data submitted for this product follow similar methods as the data submitted to support the claim on the PUMA label and, as such, should support identical label claims.

e) i. The application instructions for food contact sanitization and biofilm disinfection both require precleaning prior to application. The first step of the application instructions for biofilm disinfection state "Preclean surfaces per the Precleaning Instructions…" and the application instructions for food contact sanitization state "Apply sanitizer use solution to pre-cleaned, hard, non-porous surface…" Since the pre-cleaning instructions are not required for every application, as noted in the efficacy comments, and the pre-cleaning requirements are specifically stated in the biofilm disinfection and food contact sanitization application instructions, Sterilex believes the end-user is adequately informed of the pre-cleaning requirements.

f) i. Per the technical screen of this label amendment, all references to foaming for biofilm kill have been removed from the biofilm application instructions and the product can only be applied by pouring, wiping, brushing, scrubbing, spraying, sponging, mopping, or immersion. Sterilex does not believe it is necessary to outline application methods that are not permitted for each claim.

ii. The Ultra High Foam Additive is not intended to be a chemical foaming agent but instead is meant as an alternate brand name and alternate formulation for Ultra Activator Solution, similar to Ultra Soft Metal Activator. In order to clarify this intent, I have added this brand name at the top of page one as an optional brand name for Sterilex Ultra Activator Solution

iii. Please clarify this request. Sterilex is not aware of an EPA policy that requires specification of foam origin provided confirmatory efficacy data with foam has been submitted. In addition to historical approval of foaming, regardless of generation device, Sterilex has not seen this same label language requirement on other EPA registered product labels.

g) On June 14th, I submitted the following question to the AD Efficacy Mailbox: Sterilex has become aware of a long-standing problem in the dairy industry regarding spoilage organisms. As identified by experts in the field, dairy product quality is suffering due to

vegetative forms of spore-forming, non-public health organisms in cleaning-in-place (CIP) dairy systems. Given this need in the marketplace, would efficacy data on the vegetative forms of the bacteria be acceptable to support a non-public health claim?

On June 16th, I received the following response: Good morning, in response to your Efficacy Mailbox submission, To quickly setup the response and link it to your original inquiry, the scenario you describe seeks in essence to dissociate or unlink label claim from the efficacy data developed to support the claim undermining the relevance of the efficacy results for substantiating the claim. Label claims against spores should be substantiated with efficacy data developed against spores. Claims against vegetative cells should be substantiated with efficacy data developed against the vegetative form. This applies to all efficacy data being developed to substantiate label claims, whether public health or non-public health organisms are indicated.

Based on this response from EPA, Sterilex conducted efficacy data against the vegetative state of these 3 non-public health organisms. Per EPA's guidance, that data was not submitted because the claims were for non-public health organisms and Sterilex did not submit the data earlier in the review process because a data deficiency was not identified in the technical screen. That data is available for review if EPA would like Sterilex to submit the data at this time.

h) Sterilex requests that EPA refer to MRIDs 45611601, 45611602, 45611603, 45611604, and 45611605 to support removal of biofilms in animal drinking lines. Sterilex believes this data is sufficient to support the biofilm removal claim for both public health and non-public health biofilms from water line systems, such as animal drinking lines and dental unit water lines.

i) Please clarify this request. Sterilex was not required to specify surface temperatures when the original disinfection and sanitization claims were approved and has not seen this same surface temperature requirement on other EPA registered product labels.

j) The biofilm label claims are located on pages 18 - 21 of the product label are very clearly associated with the non-public health use sites when included on a commercial label. This section of the label, including use sites and claims, do not list public health organisms or make any claims of disinfection/sanitization associated with public health efficacy. As part of the previous amendment, Sterilex added a "Biocide and Non-Public Health Use Sites" header to this section and the word "health" to the "non-public" terms in order to re-enforce the non-public health use site designation of these claims.